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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/765,086	01/17/2001	Erkki I. Ruoslahti	P-LJ 4575	6131

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EXAMINER

YU, MISOOK

ART UNIT PAPER NUMBER

1642

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/765,086

Applicant(s)

RUOSLAHTI ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8,9,13,14,23,24 and 28-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8, 9, 13, 14, 23, 24, 28, 30, 32 is/are rejected.
- 7) ☒ Claim(s) 29,31 and 33 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Amendment filed on 9/10/2004 is acknowledged. Claims 28-33 are new. Claims 8, 9, 13, 14, 23, 24, 28-33 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, Maintained

Claims 8, 9, 13, 14, 23, and 24 remain rejected and the new claims 28, 30, 32 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As stated before in the previous Office action, this written description rejection is made due to the limitation "antimicrobial peptide having low mammalian cell toxicity when not linked to said prostate-homing peptide" in the base claims 8, 13, and 23, and also due to the new limitation "antimicrobial peptide having an amphipathic alpha-helical structure" in the new base claims 28, 30, and 32.

Since the dependent claims 9, 14, and 24 all include the limitation that lacks the written description, these dependent claims are also rejected.

Applicant argues that the specification at page 16 teaches that an antimicrobial peptide having "low mammalian cell toxicity" is not lytic to human erythrocytes or requires concentrations of greater than 100 micro molar for lytic activity. In view of this

guidance in the specification, the application satisfies the written description requirement. The specification discloses that peptides with certain formulas (note at page 7 of the Remarks section of the amendment) are expected to have alpha-helical structures. As for Javadpur et al., applicant argues that the reference finds a structure/function correlation between helicity and mammalian cytotoxicity. These arguments have been fully considered but found unpersuasive.

As for arguing with the guidance in the specification about how to screen the claimed antimicrobial peptides, i.e. an antimicrobial peptide having "low mammalian cell toxicity" is not lytic to human erythrocytes or requires concentrations of greater than 100 micro molar for lytic activity, it is noted that law requires that the disclosure of an application shall inform those skilled in the art how to make the alleged discovery, not how to screen it for themselves. As for the argument with the certain formulas, applicant is arguing limitations not present in the claims. As for the argument with Javadpur et al., clearly teach the current state of art regarding which antimicrobial peptides would have low mammalian toxicity, which high mammalian toxicity have not been teased out yet: it has be experimentally determined. In summary, the instant claims do not describe the structure of the claimed antimicrobial peptide, therefore, it is concluded that the written description requirement is still not met.

Claims 9, 14, and 24 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:207, does not reasonably provide enablement for "a functionally equivalent sequence". The

specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 9, 14, and 24 are interpreted as drawn to method involving a chimeric prostate-homing pro-apoptotic peptide, wherein the prostate-homing peptide is a "functionally equivalent sequence" of SMSIARL (SEQ ID NO: 207).

Applicant argues that "functionally equivalent sequence" means that the claimed peptide binds to the endothelium of prostate blood vessels as does peptide of SEQ ID NO:207, binds to the same receptor as does SEQ ID NO:207, the specification provides assays suitable for identifying such assays. These arguments have been fully considered but found unpersuasive for the following reasons.

As for arguing with the specification providing an assay to identify the claimed "functionally equivalent sequence", it is noted that law requires that the disclosure of an application shall inform those skilled in the art how to make the alleged discovery, not how to screen it for themselves. As for argument with the claimed "functionally equivalent sequence" binds selectively to **the same receptor** as does SMSIARL (SEQ ID NO: 207), the specification does not even teach which receptor SMSIARL (SEQ ID NO: 207) binds to. This indicates one of skill has to identify which receptor SMSIARL (SEQ ID NO: 207) binds to, first if it indeed binds to any receptor. Considering the unpredictable state of art, limited guidance, broad breath of the claims, it is concluded that undue experimentation is required to practice the invention.

Allowable Subject Matter

Claims 29, 31, and 33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey C Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



LARRY R. HELMS, PH.D
PRIMARY EXAMINER

MISOOK YU, Ph.D.
Examiner
Art Unit 1642